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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/746,635	11/13/96	MURTHY V	96700/341

HM12/0524

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EXAMINER	
GABEL,G	
ART UNIT	**PAPER NUMBER**
1641	29

DATE MAILED: 05/24/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/746,635	Murthy
Examiner	**Group Art Unit**
Gailene R. Gabel	1641

☒ Responsive to communication(s) filed on *Mar 15, 2000*

☒ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) *20* is/are pending in the applicat

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *20* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

DETAILED ACTION

Amendment Entry

1. Applicants' amendment and response filed 3/5/00 in Paper No. 28 is acknowledged and has been entered. Claim 20 has been amended. Accordingly, claim 20 is pending and under examination.

Claim Rejections - 35 USC § 112

2. In light of Applicants' amendment and arguments, the rejection of claim 20 under 35 U.S.C. 112, first paragraph, is hereby, withdrawn.

Claim Rejections - 35 USC § 103

3. Claim 20, as amended, is rejected under 35 U.S.C. 103(a) as being unpatentable over Olsson et al. (Journal of Applied Biochemistry, 5:437-445 (1983)) for reason of record.

Response to Arguments

4. A) Applicants argue that although Olsson found correlation between hemoglobin and adenylate kinase, the ratio of hemoglobin to extracellular adenylate kinase between red blood cell concentrates depicted were significantly different. Applicants point to Figure 6A and 6B, pages 442 and 445 for reference. Further, applicants argue that Olsson neither teaches nor suggests

using adenylate kinase activity for diagnosing erythrocyte hemolysis in vivo and provides no evidence to support that erythrocyte adenylate kinase activity actually correlates with hemolysis in vivo.

In response, the accumulation of adenylate kinase in Figures 6A, 6B, and 6C in the Olsson reference are effected by their difference in hematocrit (packed red cell) levels so that elevated hematocrit as in Figure 6A and 6B commands elevated accumulation of adenylate kinase activity due to increased hemoglobin leakage as compared to one with a lower hematocrit level (whole blood). Nevertheless, the ratio between adenylate kinase and hemoglobin has remained relatively constant as per Olsson whose correlation results appear to overlap with the values obtained by the applicants in the instant invention.

Moreover, while the present invention is drawn to determining adenylate kinase activity as effected by in vivo or in situ hemolysis in patients due to physiologic or pathologic causes, Olsson's study is drawn to detecting adenylate kinase activity in stored blood cells as effected by leakage of adenylate kinase from aging of erythrocytes. A person with ordinary skill in the art at the time would have appreciated the correlation between hemolysis and erythrocyte adenylate kinase suggested by Olsson as emphasized by the parallel between hemoglobin (a known indicator of hemolysis) and erythrocyte adenylate kinase. Indeed, Olsson teaches determination of erythrocytic adenylate kinase as a measure of enzymatic activity and further teaches the critical correlation between erythrocyte adenylate kinase and hemolysis regardless of the fact that the phenomenon of hemolysis occurred in vivo or in vitro. The criticality in both methods is in the

measuring of enzyme activity in adenylate kinase as it correlates to hemolysis, i.e. occurrence of "free" hemoglobin outside of an erythrocytic cell; not whether such occurrence takes place in situ or in vitro. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Olsson in determining erythrocyte adenylate kinase activity in serum rather than plasma because serum and plasma are conventional alternative sample types used in clinical analysis, differing only in the presence or absence of anticoagulation.

5. Applicants' arguments have been considered but are not deemed persuasive. Claim 20 is not allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gailene R, Gabel whose telephone number is (703) 305-0807. The examiner can normally be reached on Monday from 7:00 AM to 4:30 PM. The examiner can also be reached on alternate Fridays at 7:00 to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 4027. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

GRGabel 5/21/00

Gailene R. Gabel
Patent Examiner
Art Unit 1641

James C. Housel 5/22/00
JAMES C. HOUSEL
SUPERVISORY PATENT EXAMINER